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Via ECF and Federal Express

The Honorable F. Dennis Saylor, IV
United States District Court
Donohue Federal Building
595 Main Street
Worcester, MA 01608

Re: *Abbott GmbH & Co., KG et al. v. Centocor Ortho Biotech, Inc. et al.*, C.A. No. 4:09-cv-11340

Dear Judge Saylor:

We write in response to Centocor's letter to you of July 11, 2011, alleging that the supplemental expert report of James D. Marks, M.D. is untimely. The supplemental report was necessitated by Centocor's late disclosure of a new theory about why its product does not satisfy the "human" antibody limitation. When finally provided with a meaningful description of this theory of non-infringement in Centocor's expert reports, Abbott asked its expert Dr. Marks to provide a supplemental response. This response was completed in 6 business days and served on Centocor a week in advance of Dr. Marks' deposition.

As the Court will recall, the construction of the "human" antibody limitation was itself delayed until after the Court's Markman hearing when Centocor asserted for the first time that the term has an unduly narrow interpretation. The Court resolved the parties claim construction dispute about the term on May 5, 2010, defining "human antibody" to mean ""an antibody that is derived from human DNA and not from the DNA of any non-human species." (D.I. 162).

On May 10, Centocor essentially denied that its product met this limitation but provided no meaningful information about why. Specifically, Centocor wrote that: "CNTO 1275/Stelara is an antibody that contains at least one CDR that is derived from the DNA of a non-human species."[1] (Ex. 1, Letter from A. Verrecchio to J. Oyloe dated May 10, 2011).

On May 16, 2011, the parties filed their opening reports. Abbott's expert, Dr. Marks, filed his report on the issue of infringement and explained why Stelara literally meets the human antibody limitation. Because Centocor at this point had not provided any technical reasoning to justify its denial that Stelara met this limitation, Dr. Marks had no technical argument from Centocor to which he might have responded in his initial report.

[1] Centocor does not even specify which of the 6 possible CDRs it believes is derived from the DNA of a non-human species.

On June 10, 2011, pursuant to the Court's instruction, the parties filed supplemental contentions. (May 31, 2011, Electronic Clerk's Notes). Abbott supplemented it infringement contentions consistent with Dr. Marks opening report and consistent with this Court's definition of "human antibody." Centocor's supplement included the same uninformative denial that Stelara meets the human antibody limitation because it "contains at least one CDR that is derived from the DNA of a non-human species." (D.I. 173).

It was not until Centocor filed its non-infringement report on June 29 that it elucidated its position with any detail.[2] In particular, Centocor's expert, Dr. Siegel, set forth his belief that Stelara was not a "human antibody" because during its creation in transgenic mice it underwent processes that added small parts of the antibody that were derived from the DNA of a non-human species – the transgenic mouse.[3] The parties have since worked to firmly schedule the depositions of 12 of the 13 experts in the time period allotted for expert depositions, agreeing that Dr. Marks deposition would take place on Saturday, July 16th.[4] Abbott worked quickly with Dr. Marks to respond to Dr. Siegel's arguments and provided the supplemental report 7 days before the scheduled deposition.

Abbott, and its expert Dr. Marks, were not only entitled to supplement his opinions based on Centocor's new non-infringement theory, they were arguably required to do so under FRCP 26(e)(2). Rule 26(e)(2) states that "[f]or an expert [who must file an expert report] the party's duty to supplement extends both to information included in the report and to information given during the expert's deposition." FRCP 26(e)(2).

Centocor and Abbott have been involved in this dispute for many years, both before the United States Patent Office, and before this Court. Since January of this year, Centocor has engaged in what we believe to be a fruitless effort to contradict its numerous representations to the regulatory authorities and the general public that Stelara is a fully human antibody. Abbott has repeatedly been denied fair notice of these arguments, starting with the late interjection of a claim construction dispute and culminating with a late statement of Centocor's factual contention.

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[2] (Ex. 2, June 29, 2011, Confidential Responsive Report of Donald Siegel, M.D., Ph.D.)

[3] There are many factors that may contribute to CDR sequence alterations of germline DNA in the generation of human antibodies by a transgenic mouse. As the Siegel Responsive Report points out, some of the factors include somatic hypermutation, nucleotide base deletion, P-nucleotide addition, and N-nucleotide addition. It is unfair, as Centocor seems to imply, that Abbott should have been required to guess that Centocor would devise an argument on N-nucleotide addition that disregards the Court's claim construction ruling, especially when Stelara has been referred to as a human antibody since its discovery and even now in the marketing and regulatory related communications.

[4] Dr. Gering, Centocor's damages expert, is tentatively scheduled for July 21, 2011, however Abbott notified Centocor that it has a possible conflict with that date. (Ex. 3, July 11, 2011 Weiner letter to Verrecchio).

Before filing a supplemental report, Abbott considered asking the Court to strike Dr. Siegel's report with respect to the human antibody limitation as itself untimely given the lack of any substance to Centocor's prior statement of its position. Rather than resort to procedural technicalities, Abbott chose instead to respond on the merits. If the issue is timely notice, however, the appropriate report to strike is the report of Dr. Siegel, not Dr. Marks.

Respectfully submitted,

William G. McElwain

cc: Dianne B. Elderkin
Barbara Mullins